

## Draft Guidance on Vorapaxar Sulfate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Vorapaxar sulfate

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: EQ 2.08 mg Base  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments: Vorapaxar has a long terminal elimination half-life. Use an adequate washout period between treatments in the crossover study. You may also consider using a parallel bioequivalence study design. An AUC truncated to 72 hours may be used in place of  $AUC_{0-t}$  or  $AUC_{0-\infty}$ .

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: EQ 2.08 mg Base  
Subjects: Healthy males and nonpregnant females, general population.  
Additional Comments: See comments above.
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**Analytes to measure (in appropriate biological fluid):** Vorapaxar in plasma

**Bioequivalence based on (90% CI):** Vorapaxar

**Waiver request of in vivo testing:** Not Applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).